

Exhibit 10

1 UNITED STATES DISTRICT COURT
2 FOR THE NORTHERN DISTRICT OF OHIO
3 EASTERN DIVISION
4 IN RE: NATIONAL) MDL No. 2804
5 PRESCRIPTION OPIATE)
6 LITIGATION) Case No.
7) 1:17-MD-2804
8)
9)
10 THIS DOCUMENT RELATES TO) Hon. Dan A.
11 ALL CASES) Polster
12)
13)

14 Tuesday, May 14, 2019
15 — — —
16 HIGHLY CONFIDENTIAL - SUBJECT TO FURTHER
17 CONFIDENTIALITY REVIEW
18 — — —
19 Videotaped Deposition of JAMES E.
20 RAFALSKI, VOLUME 2, held at Weitz &
21 Luxenburg PC, 3011 West Grand Avenue, Suite
22 2150, Detroit, Michigan, commencing at
23 8:25 a.m., on the above date, before
24 Michael E. Miller, Fellow of the Academy of
25 Professional Reporters, Registered Diplomate
 Reporter, Certified Realtime Reporter and
 Notary Public.

26 — — —
27 GOLKOW LITIGATION SERVICES
28 877.370.3377 ph | fax 917.591.5672
29 deps@golkow.com

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<p>1 that. It's just that I wasn't tasked to 2 provide that methodology in regards to 3 manufacturers at this time. 4 Q. I understand. But your report 5 doesn't identify any suspicious orders that 6 were submitted by distributors to 7 manufacturers. 8 A. My report would only identify 9 those orders that the manufacturers have 10 identified. I don't make any independent 11 calculations or apply any algorithms to 12 identify it outside of what's in my report 13 stated as I've discovered as part of this 14 discovery. 15 Q. Okay. So other than the 16 reports that the manufacturers themselves 17 reported to DEA, you have not identified any 18 suspicious orders submitted by distributors 19 to manufacturers, correct? 20 A. Can I ask a clarification? Are 21 you talking about an individual order or are 22 you talking about conduct? 23 Q. I'm talking about individual 24 orders. 25 A. I have not done that as we sit</p>	<p>1 (Document review.) 2 A. I don't believe so, no, sir. 3 BY MR. O'CONNOR: 4 Q. Okay. And at trial, do you 5 intend to offer any opinion regarding whether 6 any particular order submitted to a 7 manufacturer was suspicious? 8 A. If I'm requested to do that 9 analysis by counsel, I guess that would be a 10 possibility. I haven't done the analysis as 11 today, so I couldn't offer that opinion. 12 Q. So as you sit here today, you 13 do not have an opinion on whether any 14 particular order that was shipped by a 15 manufacturer was suspicious? 16 A. I think I have an opinion. 17 Q. But you haven't identified any 18 order, correct? 19 A. I have not identified a 20 specific order, but I have an opinion on the 21 conduct. 22 Q. And are you offering any 23 opinion in this litigation that any 24 particular order that was shipped into Summit 25 or Cuyahoga Counties was suspicious?</p>
<p>1 here today, no, sir. 2 Q. Okay. So your report does not 3 identify any shipments by manufacturers to 4 distributors that you claim should have been 5 reported as suspicious? 6 A. My opinion goes to whether or 7 not there were effective -- or suspicious 8 orders, effective suspicious order systems in 9 place and/or the maintenance of effective 10 controls, the due diligence. I do not do any 11 calculations that would identify any specific 12 orders. 13 Q. Okay. So just to be clear, in 14 response to my question, your report does not 15 identify any shipments by manufacturers to 16 distributors that you claim should have been 17 reported as suspicious, correct? 18 A. I think there's some instances 19 in my report, there was -- there may be a 20 description of a relationship or some 21 transactions between a -- let me think a 22 second. 23 Q. Uh-huh. 24 A. Because I have all of the 25 different companies.</p>	<p>1 Page 633 2 A. Yes. 3 Q. Okay. And are you offering any 4 opinion in this litigation that any 5 particular order shipped by a manufacturer 6 into Summit or Cuyahoga County was 7 suspicious? 8 A. I'm sorry, shipped by a 9 manufacturer -- 10 Q. Correct. 11 A. -- to a distributor? 12 Q. That's right. To -- to someone 13 in Cuyahoga or Summit County. 14 A. No, sir. 15 Q. Okay. With respect to a 16 manufacturer, what is a suspicious order? 17 A. Well, if a manufacturer has 18 conducted a sufficient due diligence or 19 onboarding process and they've evaluated the 20 scope of their customers' business and the 21 needs, they would establish a pattern, and 22 that pattern would give them an idea of 23 initially the volume of drugs they need to 24 purchase. 25 Now, if it's brand-new customer -- yours is kind of a hypothetical.</p>

<p style="text-align: right;">Page 636</p> <p>1 If it's a brand-new customer, there's not a 2 pattern or a frequency, but they would start 3 out with what they assess as a legitimate 4 volume, and they would monitor that volume, 5 and if a customer exceeded that, that should 6 trigger as an unusual size. 7 But to give you just a general 8 definition, it's kind of a broad topic 9 because it depends on the scope of business 10 of the manufacturer, of the customer, the 11 type of products, the needs, so the -- prior 12 to ever shipping an order, the importance is 13 to understand what the legitimate needs is of 14 a customer.</p> <p>15 Q. Yesterday you testified that it 16 was important to understand what a usual 17 order was so that you could determine what a 18 suspicious order was.</p> <p>19 Do you generally recall that 20 testimony?</p> <p>21 A. I think that's a general 22 description. I think we were discussing the 23 size, so I think before you would know an 24 unusual size, you would need to know the 25 usual size.</p>	<p style="text-align: right;">Page 638</p> <p>1 baseline information to get a gauge on how 2 much product you'd want to send to them. I 3 don't think you would just send them an 4 amount of product and hope they distribute 5 it. I think there should be some kind of a 6 relationship and identification of a 7 legitimate total. 8 BY MR. O'CONNOR: 9 Q. Besides understanding what type 10 of pharmacy -- or what type of customer or 11 the number of customers a distributor had, 12 what other information would you say a 13 manufacturer needs to know in order to 14 establish a baseline? 15 A. A baseline in regards to size? 16 Q. Correct. 17 A. Well, I think there would be 18 some other factors that they should minimally 19 look at. That would be the ability for the 20 company to actually handle the volume of 21 product on a security aspect, they had 22 sufficient cage or vault depending on the 23 schedule of controlled substance they were 24 purchasing. 25 I think they may want to do</p>
<p style="text-align: right;">Page 637</p> <p>1 And I think that's kind of the 2 simpler way of what I just said, is that if 3 you don't really have a comprehension of what 4 is the legitimate needs of your customer, 5 then you couldn't know an unusual order -- 6 unusual size of an order, I'm sorry.</p> <p>7 Q. What information would you need 8 to determine what a usual order looked like 9 for a manufacturer?</p> <p>10 MR. FULLER: Form.</p> <p>11 THE WITNESS: I'm sorry, you 12 said something?</p> <p>13 MR. FULLER: Object to form.</p> <p>14 THE WITNESS: Oh. Sorry.</p> <p>15 A. I think that's dependent on the 16 skill of your compliance employees. I think 17 you go in and evaluate the distributor. I 18 don't think the distributor would purchase a 19 manufacturer's product with an idea on how 20 they were going to sell it and market it, and 21 I think you would evaluate what their scope 22 of business is and the type of customers they 23 were; how many pharmacies they could 24 distribute to.</p> <p>25 I think you'd have to get some</p>	<p style="text-align: right;">Page 639</p> <p>1 some analysis of the identifications of the 2 pharmacies, if possible, because it's a 3 potential that in the case of Mallinckrodt, 4 they might already have information about the 5 distribution amounts or the purchase amounts 6 for those pharmacies and some trends.</p> <p>7 Might do some comparison to 8 like customers. Might look into the 9 geographic location of where the product is 10 intended to be distributed. At least for the 11 Mallinckrodt products, to confirm or deny 12 there might be an issue of a distribution by 13 volume to those specific areas.</p> <p>14 I think the essential thing is 15 what I said initially. I think you need to 16 get an idea of how many customers that that 17 distributor intends to distribute.</p> <p>18 And I think if we're talking 19 about the onboarding or the initial amounts 20 that they'll be distributing, I think that a 21 registrant should follow those pretty closely 22 because my experience would indicate that 23 sometimes other registrants aren't that 24 truthful, and not just because they want to 25 divert, although that's one of the</p>

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<p>1 recollection is they did not implement their 2 system.</p> <p>3 Q. What do you mean they didn't 4 implement their system?</p> <p>5 A. Buzzeo was not retained as a 6 consultant and the Buzzeo system was not 7 implemented at the company.</p> <p>8 Q. And at that time, he was 9 reviewing the Suspicious Orders I system for 10 Teva, correct?</p> <p>11 A. I think that's an accurate 12 statement, yes.</p> <p>13 Q. And at no point does the report 14 conclude that Teva's suspicious order 15 monitoring system was not compliant with DEA 16 regulations; isn't that a correct statement?</p> <p>17 A. Say that again.</p> <p>18 Q. At no point in Mr. Buzzeo's 19 report does he conclude that the Teva 20 suspicious order monitoring system was not 21 compliant with DEA regulations; wouldn't you 22 agree?</p> <p>23 A. I think -- I think he was 24 critical of the functionality of it, but in 25 reading other reports by Mr. Buzzeo, I don't</p>	<p>1 A. I believe he did make that 2 comment, yes. He didn't say that it was 3 sufficient to be compliant, but he did say it 4 was an improvement.</p> <p>5 Q. But again, he didn't say that 6 it wasn't compliant with DEA regulations?</p> <p>7 A. No, I didn't say that.</p> <p>8 Q. My question to you is: He 9 didn't say that it wasn't compliant with DEA 10 regulations?</p> <p>11 A. He never made that exact 12 statement.</p> <p>13 Q. Teva also had an internal audit 14 of its own suspicious order monitoring 15 program?</p> <p>16 A. I believe so, yes.</p> <p>17 Q. And that program was rated 18 overall as effective, correct?</p> <p>19 A. Yes, but it's an internal 20 audit.</p> <p>21 Q. The DEA regulations don't 22 require that companies actively audit their 23 own programs, correct?</p> <p>24 A. No, that's true. But I only 25 make that statement because sometimes the</p>
<p style="text-align: center;">Page 821</p> <p>1 think he draws -- makes that conclusion. At 2 least he doesn't put it in his reports, 3 because he's not a DEA representative.</p> <p>4 Q. The DEA regulations don't state 5 what type of suspicious order monitoring 6 model a registrant has to use; isn't that 7 correct?</p> <p>8 A. No, it's up to the registrant 9 to design their system that meets their 10 business needs and accomplishes the 11 identification of suspicious orders.</p> <p>12 Q. And it doesn't state anything 13 about what standard deviations or what number 14 of standard deviations a registrant should 15 use in its algorithm for monitoring 16 suspicious orders?</p> <p>17 A. It does not give guidance in 18 that area.</p> <p>19 Q. At the time the Buzzeo 20 report -- I'm sorry, strike that.</p> <p>21 The Buzzeo report concluded 22 that SORDS II, which is an improvement on the 23 SORDS I suspicious order monitoring program, 24 that Teva had in place was an improvement 25 over SORDS I; isn't that correct?</p>	<p style="text-align: center;">Page 823</p> <p>1 person that does the audit, without knowing 2 the full information on the audit, is the 3 person in charge of the system, so they don't 4 typically give a bad audit to themselves.</p> <p>5 So, I mean, I'm not totally 6 discounting it, but I'm always concerned 7 about internal audits.</p> <p>8 Q. Mr. Rafalski, in your report 9 you don't identify any suspicious order that 10 Teva shipped to Summit County or Cuyahoga; 11 isn't that correct?</p> <p>12 A. I do not identify any single 13 suspicious order -- any order specifically 14 that was suspicious.</p> <p>15 Q. And that goes for Cephalon and 16 the Actavis entities as well, correct?</p> <p>17 A. As I sit here today, that's an 18 accurate statement.</p> <p>19 Q. And you don't identify any 20 order that Teva failed to flag as suspicious?</p> <p>21 A. Is that question a specific 22 order?</p> <p>23 Q. Any order that Teva failed to 24 flag as suspicious, you don't have an example 25 of any specific order?</p>

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<p>1 A. No, I think my examples in here 2 are more -- go more to the conduct of the due 3 diligence and it doesn't specifically say 4 that there was a specific order, but I think 5 the totality of the incident that I describe 6 on page 183 I think would include that, but 7 to answer your question, there's no specific 8 order where I state that.</p> <p>9 Q. And I want to ask you quickly 10 about that order.</p> <p>11 You're speaking of the Publix 12 Supermarket pharmacies incident or scenario 13 that we discussed -- that's in your report on 14 page 183?</p> <p>15 A. Yes, I am.</p> <p>16 Q. The orders involving the Publix 17 Supermarket pharmacies were not orders placed 18 from Publix to Teva, were they?</p> <p>19 A. No, they were placed to a 20 distributor, an in-between so --</p> <p>21 Q. Right. They were orders placed 22 from Publix to Anda, correct?</p> <p>23 A. Yes. But so the first concern 24 that I would have with this is that Teva 25 would need a means of effective controls to</p>	<p>1 looking at those because Anda is his 2 customer, correct?</p> <p>3 A. Yes.</p> <p>4 Q. Right. And he was looking at 5 Publix's forecasting data, correct?</p> <p>6 A. Yes.</p> <p>7 MR. FULLER: Counsel, I believe 8 the 14 hours is up.</p> <p>9 MS. BARBER: All right. At 10 this time I am going to reserve my 11 time. I haven't had -- along with my 12 colleagues, haven't had adequate time 13 to ask questions of Mr. Rafalski, 14 which is a violation of our clients' 15 due process, and we reserve any 16 additional time in the future to 17 examine Mr. Rafalski or reexamine 18 Mr. Rafalski.</p> <p>19 MS. SWIFT: Before we break, 20 I'd like to put one additional thing 21 on the record.</p> <p>22 Mr. Rafalski, you said your 23 method for assessing the defendants' 24 suspicious order monitoring system is 25 based on your experience, training and</p>
<p style="text-align: center;">Page 825</p> <p>1 go to Anda and see why this situation 2 occurred.</p> <p>3 Q. And it did do that, correct?</p> <p>4 A. I don't recall that occurring.</p> <p>5 Q. Well, so you read the 6 deposition of Joe Tomkiewicz, didn't you?</p> <p>7 A. Yes.</p> <p>8 Q. And sitting here today, you 9 don't know whether any of Teva's product was 10 ultimately shipped to one of those Publix 11 Supermarkets that Joe Tomkiewicz identified 12 as entities he wanted to look into, correct?</p> <p>13 A. Based on my review, he was 14 looking at the chargebacks, and I believe 15 they were Teva products.</p> <p>16 Q. But you would agree with me 17 that Joe Tomkiewicz testified he didn't see 18 any specific orders of Teva's products, 19 correct?</p> <p>20 A. Yes, but if they weren't Teva's 21 products, I'm not sure that he would have 22 taken all this action unless he was 23 indicating it was someone else's product that 24 he was going to go investigate.</p> <p>25 Q. Well, he could have been</p>	<p style="text-align: center;">Page 827</p> <p>1 legal guidance from lawyers at the 2 DEA.</p> <p>3 Just yes or no, does your Touhy 4 authorization --</p> <p>5 MR. FULLER: Don't answer this 6 question.</p> <p>7 MS. SWIFT: -- prevent you from 8 disclosing the legal guidance from DEA 9 lawyers that supports your opinion?</p> <p>10 MR. FULLER: Don't answer the 11 question. She's over her time.</p> <p>12 Off the record.</p> <p>13 THE VIDEOGRAPHER: Going off 14 the record, 4:52 p.m.</p> <p>15 (Recess taken, 4:52 p.m. to 16 4:52 p.m.)</p> <p>17 (The following proceedings were 18 conducted off the videotaped record.)</p> <p>19 MR. MATTHEWS: Good afternoon. 20 This is James Matthews. I represent 21 Anda Inc. I've sat here for two days 22 at this deposition and have not asked 23 any questions because the name Anda 24 doesn't appear in your report.</p> <p>25 However, in the last series of</p>